Summary of the Office Action

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth jn section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

THE FACTUAL INQUIRIES
Graham v. *John Deere Co.,* 383 U.S. 1, 148; USPQ 459 (1966),

1. Determining the scope and contents of the prior art.

2.Ascertaining the differences between the prior art and the claims at issue

3 Resolving the level of ordinary skill in the pertinent art.

4.Considering objective evidence present in the application indicating obviousness or nonobviousness.

THE REJECTION

Claims 1-20 previousl were rejected under 35 U.S.C. 103(a) as being unpatentable over Chandrasekaran (US 4,286,592) in view of Tawashi (US 5,648,101). Claims 11-20 now have been rejected on reference Tawashi (US 5,648,101).

APPLICANT'S CLAIMS

A transdermal patch comprising a drug reservoir layer 14 containing a hematinic substance., a rate;controlling membrane 13 secured to the reservoir layer 14 and a contact adhesive 12

scope and content of the prior art(MPEP §2141.01)

Tawashi teaches, in example 9, column 10. lines 11-19, a transdermal patch. for the **transdermal delivery of NO (Nitrous Oxide) to a situs** on animal skin. A pressure sensitive patch or laminate of an inert foraminous or porous inert cellulose matrix impregnated with ferrous sulfate solution (for releasing nitrous oxide) in an amount or rate of 0.025 mM/square cm. and covered with an outer water resistant foil web. The patch is activated by treatment with 50 microlitres of sodium nitrite solution in water (1M) and immediately **applied to the skin**

where NO gas is released in situ.

Chandrasekaran discloses in his Figure 1 a transdermal device comprising a backing layer 11, a drug reservoir layer 12 (composed of *a* drug 13 dispersed in a carrier 14) , *a* contact adhesive layer 15 and a release liner layer 16.(col. 2, lines 54-60). The backing layer can comprise an aluminized polyester film and the coating layer comprising siliconized polyester (example 1, col. 4, lines 38-39,47-48 and example 2, col. 5, lines 15-16, 2223). The drug reservoir can comprise silicone-based carriers or carriers made frommixtures of mineral oil and polyisobutenes (col. 3, lines 35-36), It is taught by example 1 that the transdermal delivery devrce is at leas! 0.1 mil) thick. **Chandrasekaran does not have a rate controlling memberane**

difference between the prior art and the *claims* (MPEP §2141.02)

The prior art reference, Tawashi teaches a transdermal patch. for the **transdermal delivery of NO (Nitrous Oxide) to a situs** on animal skin, and does not teach the use of a hematinic substance to treat iron deficiency.

The prior art reference, Chandrasekaran, does not teach **a rate controlling memberane or the use of** the hematinic substance as described in claims 2 and 14 or using the device to treat iron deficiency.

non obviousness of the invention (MPEP §2142M2143)

It would NOT have been obvious to one of ordinary skill in the art at the time the invention was made to use Tawashi who teaches only that ferrous sulfate can be formulated into a transdermal patch and can be used with a sodium nitrite solution in water to release nitrous oxide gas The expected result of combining the teachings of the references would be to use a transdermal patch to release nitrous oxide.

Nor would it have been obvious to combine Tawashi with Chandrasekaran.
Not only is Chandrasekaran is silent with respect to the preferred drug, Tawashi does not teach the use of a hematinic substance for treatment of an iron deficiency.

The Specific Difference Between The Invention And The Cited Art

Claim 11

This claim distinguishes over the references by providing a method of treating an iron deficiency by (a) providing a drug reservoir layer containing an hematinic substance; and (b)securing said drug reservoir layer to a skin surface. The references do not provide any such method.

Claim 12

This claim distinguishes over the references by the step of applying a rate-controlling membrane to the reservoir layer. This neither disclosed nor suggested by the references.

Claim 13

This claim distinguishes over the references by the step of applying a contact adhesive to the rate-controlling membrane. This neither disclosed nor suggested by the references.

Claim 14

This claim distinguishes over the references by selecting the hematinic substance from the class consisting of ferrous sulfate, ferrous lactate, ferrous iodide, ferrous gluconate, ferrous fumarate, ferrous citrate, ferrous carbonate saccharated, ferrous carbonate mass, ferronascin, ferroglycine sulfate, and ferrocholinate. This neither disclosed nor suggested by the references.

Claim 15

This claim distinguishes over the references by its dependency on a parent claim and includes the step of including a protective peel strip on the contact adhesive.

Claim 16

This claim distinguishes over the references by its dependency on a parent claim and requires the step of including a backing layer upon the drug reservoir layer.

Claim 17

This claim distinguishes over the references by he step of including a hematinic substance in the contact adhesive. This neither disclosed nor suggested by the references.

Claim 18

This claim distinguishes over the references by its dependency on a parent claim and provides the backing layer as aluminized polyester film.

Claim 19

This claim distinguishes over the references by its dependency on a parent claim and includes the step of providing said drug reservoir with mineral oil and polyisobutylene.

Claim 20

This claim distinguishes over the references by requiring that a drug reservoir layer contain an hematinic substance; and applying the layer to a rate-controlling membrane. This is neither disclosed nor suggested by the references.

Claim 21

This claim distinguishes over the references by requiring a rate-controlling membrane secured to a reservoir layer containing an hematinic substance. This is neither disclosed nor suggested by the references.

Claim 22

This claim distinguishes over the references by requiring hematinic substance selected from the class consisting of ferrous sulfate, ferrous lactate, ferrous iodide, ferrous gluconate, ferrous fumarate, ferrous citrate, ferrous carbonate saccharated, ferrous carbonate mass, ferronascin, ferroglycine sulfate, and ferrocholinate. This neither disclosed nor suggested by the references.

Claim 23

This claim distinguishes over the references by its dependency on a parent claim and requires a protective peel strip on the contact adhesive.

Claim 24

This claim distinguishes over the references by its dependency on a parent claim and requires a backing layer upon the drug reservoir layer.

Claim 25

This claim distinguishes over the references by further including a hematinic substance in the contact adhesive. This neither disclosed nor suggested by the references.

Claim 26

This claim distinguishes over the references by its dependency on a parent claim and requires a backing layer of aluminized polyester film.

Claim 27

This claim distinguishes over the references by its dependency on a parent claim and requires the drug reservoir to include mineral oil and polyisobutylene.

Claim 28

This claim distinguishes over the references by requiring that the contact adhesive include mineral oil and polyisobutylene. This neither disclosed nor suggested by the references.

Claim 29

This claim distinguishes over the references by its dependency on a parent claim and requires a protective peel strip of siliconized polyester.

Claim 30

This claim distinguishes over the references by requiring patch is a film with a plurality of layers and ranges in thickness from .1 mm to .3 mm. This neither disclosed nor suggested by the references.

The Fax of 9-28-07 from the Examiner

Katherine Aldred

From: "George, Konata" <Kanata.George@USPTO.GOV>
To: <riteloans1 Gcomcast.net>
Sent: Friday, September 28, 2007 1:48 AM
Subject: *10/642,646*

Katherine Aldred,

To make the record straight he is what needs to be done.

1) The claims need to have the proper claim status identifier i.e.
Claims 1-10 (Canceled)
Claims 11 -20 can be copied just as they are in the response filed November 14, 2006.

2) Resend the "Applicants Arguments/Remarks" as filed on April 30, 2007

This should clear the record and help move the application to the next step.

Any further questions feel free to call me.

Konata M. George
Patent Examiner
Art Unit 1616
Rensem 4 A 48
571.272.0613

This response is believed to meet the requirements imposed by the Examiner

CONCLUSION

With the explanation that has been provided showing how the claims define the invention over the cited references, taken in combination, it is believed that the application is in condition for allowance

Respectfully submitted,

/s/*Katherine M. Aldred*
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